

(2) Offerors may also contact the following office to obtain information about the regulations for the protection of human subjects and related policies and guidelines: Protection of Human Subjects Coordinator, U.S. Department of Education, Office of the Chief Financial Officer, Financial Management Operations, 400 Maryland Avenue, SW., Washington, DC 20202-4331, Telephone: (202) 245 8090.

(End of provision)

**3452.224-72 Research activities involving human subjects.**

As prescribed in 3424.170, insert the following clause in any contract that includes research activities involving human subjects covered under 34 CFR part 97:

**RESEARCH ACTIVITIES INVOLVING HUMAN SUBJECTS (MAR 2011)**

(a) In accordance with Department of Education regulations on the protection of human subjects in research, title 34, Code of Federal Regulations, part 97 (“the regulations”), the contractor, any subcontractors, and any other entities engaged in covered (nonexempt) research activities are required to establish and maintain procedures for the protection of human subjects. The definitions in 34 CFR 97.102 apply to this clause. As used in this clause, *covered research* means research involving human subjects that is not exempt under 34 CFR 97.101(b) and 97.401(b).

(b) If ED determines that proposed research activities involving human subjects are covered (*i.e.*, not exempt under the regulations), the contracting officer or contracting officer’s designee will require the contractor to apply for the Federal Wide Assurance from the Office for Human Research Protections, U.S. Department of Health and Human Services, if the contractor does not already have one on file. The contracting officer will also require that the contractor obtain and send to the Department documentation of Institutional Review Board (IRB) review and approval of the research.

(c) In accordance with 34 CFR part 97, all subcontractors and any legally separate entity (neither owned nor operated by the contractor) that will be engaged in covered research activities under or related to this contract shall be required to comply with the requirements for assurances and IRB approvals. The contractor must include the substance of this clause, including paragraph (c) of this clause, in all subcontracts, and must notify any other entities engaged in the covered research activities of their responsibility to comply with the regulations.

(d) Under no condition shall the contractor conduct, or allow to be conducted, any cov-

ered research activity involving human subjects prior to the Department’s receipt of the certification that the research has been reviewed and approved by the IRB. (34 CFR 97.103(f).) No covered research involving human subjects shall be initiated under this contract until the contractor has provided the contracting officer (or the contracting officer’s designee) a properly completed certification form certifying IRB review and approval of the research activity, and the contracting officer or designee has received the certification. This restriction applies to the activities of each participating entity.

(e) In accordance with 34 CFR 97.109(e), an IRB must conduct continuing reviews of covered research activities at intervals appropriate to the degree of risk, but not less than once a year. Covered research activities that are expected to last one year or more are therefore subject to review by an IRB at least once a year.

(1) For each covered activity under this contract that requires continuing review, the contractor shall submit an annual written representation to the contracting officer (or the contracting officer’s designee) stating whether covered research activities have been reviewed and approved by an IRB within the previous 12 months. The contractor may use the form titled “Protection of Human Subjects: Assurance Identification/Certification/Declaration of Exemption” for this representation. For multi-institutional projects, the contractor shall provide this information on its behalf and on behalf of any other entity engaged in covered research activities for which continuing IRB reviews are required.

(2) If the IRB disapproves, suspends, terminates, or requires modification of any covered research activities under this contract, the contractor shall immediately notify the contracting officer in writing of the IRB’s action.

(f) The contractor shall bear full responsibility for performing as safely as is feasible all activities under this contract involving the use of human subjects and for complying with all applicable regulations and requirements concerning human subjects. No one (neither the contractor, nor any subcontractor, agent, or employee of the contractor, nor any other person or organization, institution, or group of any kind whatsoever) involved in the performance of such activities shall be deemed to constitute an agent or employee of the Department of Education or of the Federal government with respect to such activities. The contractor agrees to discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the contractor and its employees.

## Department of Education

3452.227-72

(g) Upon discovery of any noncompliance with any of the requirements or standards stated in paragraphs (b) and (c) of this clause, the contractor shall immediately correct the deficiency. If at any time during performance of this contract, the contracting officer determines, in consultation with the Protection of Human Subjects Coordinator, Office of the Chief Financial Officer, or the sponsoring office, that the contractor is not in compliance with any of the requirements or standards stated in paragraphs (b) and (c) of this clause, the contracting officer may immediately suspend, in whole or in part, work and further payments under this contract until the contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.

(h) The Government may terminate this contract, in full or in part, for failure to fully comply with any regulation or requirement related to human subjects involved in research. Such termination may be in lieu of or in addition to suspension of work or payment. Nothing herein shall be construed to limit the Government's right to terminate the contract for failure to fully comply with such requirements.

(i) The regulations, and related information on the protection of human research subjects, can be found on the Department's protection of human subjects in research Web site: <http://ed.gov/about/offices/list/ocfo/humansub.html>.

Contractors may also contact the following office to obtain information about the regulations for the protection of human subjects and related policies and guidelines: Protection of Human Subjects Coordinator, U.S. Department of Education, Office of the Chief Financial Officer, Financial Management Operations, 400 Maryland Avenue, SW., Washington, DC 20202-4331, Telephone: (202) 245-8090.

(End of clause)

### 3452.227-70 Publication and publicity.

As prescribed in 3427.409, insert the following clause in all solicitations and contracts other than purchase orders:

#### PUBLICATION AND PUBLICITY (MAR 2011)

(a) Unless otherwise specified in this contract, the contractor is encouraged to publish and otherwise promote the results of its work under this contract. A copy of each article or work submitted by the contractor for publication shall be promptly sent to the contracting officer's representative. The contractor shall also inform the representative when the article or work is published and furnish a copy in the published form.

(b) The contractor shall acknowledge the support of the Department of Education in

publicizing the work under this contract in any medium. This acknowledgement shall read substantially as follows:

"This project has been funded at least in part with Federal funds from the U.S. Department of Education under contract number [Insert number]. The content of this publication does not necessarily reflect the views or policies of the U.S. Department of Education nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."

(End of clause)

### 3452.227-71 Advertising of awards.

As prescribed in 3427.409, insert the following clause in all solicitations and contracts other than purchase orders:

#### ADVERTISING OF AWARDS (MAR 2011)

The contractor agrees not to refer to awards issued by, or products or services delivered to, the Department of Education in commercial advertising in such a manner as to state or imply that the product or service provided is endorsed by the Federal government or is considered by the Federal government to be superior to other products or services.

(End of clause)

### 3452.227-72 Use and Non-Disclosure Agreement.

As prescribed in 3427.409, insert the following clause in all contracts over the simplified acquisition threshold, and in contracts under the simplified acquisition threshold as appropriate:

#### USE AND NON-DISCLOSURE AGREEMENT (MAR 2011)

(a) Except as provided in paragraph (b) of this clause, proprietary data, technical data, or computer software delivered to the Government with restrictions on use, modification, reproduction, release, performance, display, or disclosure may not be provided to third parties unless the intended recipient completes and signs the use and non-disclosure agreement in paragraph (c) of this clause prior to release or disclosure of the data.

(1) The specific conditions under which an intended recipient will be authorized to use, modify, reproduce, release, perform, display, or disclose proprietary data or technical data subject to limited rights, or computer software subject to restricted rights must be stipulated in an attachment to the use and non-disclosure agreement.

(2) For an intended release, disclosure, or authorized use of proprietary data, technical data, or computer software subject to special